

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P.,)	
PURDUE PHARMACEUTICALS L.P.,)	
THE P.F. LABORATORIES, INC., and)	
GRÜNENTHAL GMBH,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 15-687 (GMS)
)	
ALVOGEN PINE BROOK, INC.,)	
)	
Defendant.)	

JOINT STATUS REPORT

Plaintiffs Purdue Pharma L.P., Purdue Pharmaceuticals L.P., The P.F. Laboratories, Inc. (collectively, “Purdue”), and Grünenthal GmbH (“Grünenthal”; together with Purdue, the “Plaintiffs”), along with Defendant Alvogen Pine Brook, Inc. (the “Defendant” or “Alvogen”; together with Plaintiffs, the “Parties”), submit the following Joint Status Report. The Parties’ proposed case schedule is attached hereto as Exhibit A.

1. Jurisdiction And Service

The Parties agree that this Court has subject matter jurisdiction over the Plaintiffs’ claims pursuant to 28 U.S.C. §§ 1331 and 1338(a) and the Defendant’s counterclaims pursuant to 28 U.S.C. §§ 2201 and 2202. For purposes of this action, the Parties do not challenge personal jurisdiction in Delaware.

Alvogen has been served with the Summons and Complaint in this action.

2. Substance Of The Action

This is a patent infringement case brought pursuant to the patent laws of the United States and the Hatch-Waxman Act.

a. Plaintiffs' Statement Of Allegations

Purdue Pharma L.P. asserts that it is the owner of U.S. Patent Nos. 6,733,783 (“the ‘783 patent”), 8,361,499 (“the ‘499 patent”), 8,551,520 (“the ‘520 patent”), 8,647,667 (“the ‘667 patent”), 9,023,401 (“the ‘401 patent”), and 8,808,740 (“the ‘740 patent”), and that it is an exclusive licensee of U.S. Patent No. 8,309,060 (“the ‘060 patent”) (collectively, the “patents-in-suit”). Purdue Pharma L.P., Purdue Pharmaceuticals L.P., and The P.F. Laboratories, Inc. assert that they are the owners of U.S. Patent No. 8,529,948 (“the ‘948 patent”). The ‘783 patent, the ‘499 patent, the ‘520 patent, the ‘667 patent, the ‘401 patent, the ‘948 patent, the ‘740 patent, and the ‘060 patent, collectively, are the “patents-in-suit.” Grünenthal asserts that it is the owner of the ‘060 patent. Purdue Pharma L.P. asserts that it is the holder of FDA-approved New Drug Application No. 206627 for Hysingla[®] ER (hydrocodone bitartrate) (“Hysingla[®]”) indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment in patients for whom alternative treatment options are inadequate. Plaintiffs allege on information and belief that Alvogen infringed the patents-in-suit under 35 U.S.C. § 271(e)(2) by filing Abbreviated New Drug Application (“ANDA”) No. 208269, with a Paragraph IV certification, seeking approval to market generic versions of Hysingla[®] (the “Alvogen Generic Product”) prior to the expiration of the patents-in-suit. Plaintiffs further allege that Alvogen’s commercial manufacture, use, offer for sale, sale and importation of the Alvogen Generic Product prior to expiration of the patents-in-suit will directly infringe the patents-in-suit under 35 U.S.C. § 271(a) and will, under §§ 271(b) and (c), induce and contribute to direct infringement by patients, caregivers, and other end users.

Plaintiffs commenced this action within forty-five (45) days of receiving Alvogen’s notice of Paragraph IV certification on or about June 22, 2015, which (i) permits

Plaintiffs to obtain, by discovery, the documents and physical samples necessary to confirm their belief that the proposed commercialization of the Alvogen Generic Product will infringe the patents-in-suit, and (ii) invoked the 30-month stay provided for under the Hatch-Waxman Act. The 30-month stay in this action currently runs to or about December 22, 2017.

b. Defendant's Statement Of Defenses And Counterclaims

Alvogen filed ANDA No. 208269 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale or importation of the Alvogen Generic Product. Alvogen admits that Alvogen's ANDA No. 208269 contains a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging, *inter alia*, that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale or importation of the drug products described in Alvogen's ANDA. Alvogen admits that it sent a notice letter dated June 19, 2015 addressed to the Plaintiffs certifying that the manufacture, use, sale, offer for sale or importation of Alvogen's Generic Product will not infringe any valid claim of the patents-in-suit.

Alvogen asserts that each claim of the patents-in-suit is invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including §§ 101, 102, 103, 112 and/or the judicial doctrine barring double-patenting. Alvogen further asserts that the commercial manufacture, use, sale, offer for sale, and/or importation of Alvogen's Generic Product does not infringe and will not infringe, either directly or by contribution or inducement, literally or by the doctrine of equivalents, any valid and enforceable claim of the patents-in-suit. Alvogen also asserts that submission of Alvogen's ANDA No. 208269 has not infringed and is not infringing any claim of the patents-in-suit under 35 U.S.C. § 271(e).

3. Identification Of Issues

a. Related Cases and Possible Additional Suits

This lawsuit is one of three pending related cases as discussed below in Section 12.

b. Plaintiffs' Position

At a minimum, Plaintiffs will raise the following factual and legal issues in this case: (i) whether Alvogen's filing of ANDA No. 208269 infringed one or more claims of the patents-in-suit; (ii) whether the Alvogen Generic Product as made, imported, offered for sale or sold by Alvogen will infringe the patents-in-suit; (iii) whether the Alvogen Generic Product will infringe the patents-in-suit when used by patients, caregivers, or other end users; and (iv) whether the manufacture, use, sale, offer for sale or importation of the Alvogen Generic Product will directly infringe the patents-in-suit or induce or contribute to infringement of the patents-in-suit.

c. Defendant's Position

At a minimum, Alvogen will raise the following factual and legal issues in this case: (i) whether Alvogen's filing of ANDA No. 208269 infringed one or more claims of the patents-in-suit; (ii) whether manufacture, use, offer for sale, sale and importation of Alvogen's Generic Product infringes any valid claim of the patents-in-suit; and (iii) whether each claim of the patents-in-suit is invalid.

4. Narrowing Of Issues

The Parties have not identified issues ripe for narrowing at this early stage in the case. Discovery will be required to determine which issues, if any, might be narrowed going forward. The Parties will continue to evaluate the issues before them to determine if and when such narrowing can be accomplished.

Certain claims of Grünenthal's '060 patent recently were held invalid for obviousness in an unrelated case, *Endo Pharmaceuticals Inc. and Grünenthal GmbH v. Teva Pharmaceuticals USA, Inc., et al.*, 1:12-cv-08060/8317, 1:13-cv-435/436-TPG-GWG (S.D.N.Y.). Grünenthal et al. appealed that decision on September 11, 2015. Based upon statistics available on the Federal Circuit's website concerning the time for processing appeals,¹ Grünenthal expects that the appeal will be decided well before trial or even the close of discovery in this case. Accordingly, Grünenthal proposes to stay proceedings concerning the '060 patent, including all discovery and all other items listed in the proposed case schedule attached hereto as Exhibit A, pending disposition of Grünenthal's appeal. Grünenthal further asserts that the agreements herein should not pertain to discovery regarding the '060 patent. Alvogen opposes any stay of the present proceedings as related to the '060 patent, including any discovery and all other items listed in the proposed case schedule attached hereto as Exhibit A.

5. Relief

a. Plaintiffs' Request For Relief

Plaintiffs have requested that this Court: (i) adjudge that Defendant has infringed one or more claims of each of the '783, '499, '520, '667, '401, '948, '740, and '060 patents, and that the commercial sale, offer for sale, use, importation, and/or manufacture of Alvogen Generic Product would infringe, induce infringement of, and/or contribute to the infringement of one or more claims of each of the '783, '499, '520, '667, '401, '948, '740, and '060 patents; (ii) adjudge, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 208269 and Alvogen Generic Product, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date no earlier than the last date of expiration of the '783, '499,

¹ <http://www.cafc.uscourts.gov/the-court/statistics>.

'520, '667, '401, '948, '740, and '060 patents, plus any additional periods of extension or exclusivity attached thereto; (iii) preliminarily and permanently enjoin, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Defendant, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product that is the subject of ANDA No. 208269, including Alvogen Generic Product or any other drug product that infringes the '783, '499, '520, '667, '401, '948, '740, and '060 patents; (iv) declare this an exceptional case and award Plaintiffs their attorneys' fees and costs, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and (v) award Plaintiffs such other and further relief as this Court may deem just and proper.

b. Defendant's Request For Relief

Alvogen has requested that this Court: (i) dismiss the Complaint with prejudice, and that the Plaintiffs take nothing by their Complaint; (ii) declare that the manufacture, use, offer for sale, sale and importation of Alvogen's Generic Product does not and will not infringe any valid claim of the '783, '499, '520, '667, '401, '948, '740, and '060 patents; (iii) declare that the submission of ANDA No. 208269 by Alvogen does not infringe any valid and enforceable claim of the '783, '499, '520, '667, '401, '948, '740, and '060 patents; (iv) declare that the claims of the '783, '499, '520, '667, '401, '948, '740, and '060 patents are invalid; (v) declare that this is an exceptional case; (vi) award Alvogen its costs, expenses and attorneys' fees pursuant to 35 U.S.C. § 285, other applicable statutes or rules, or the general power of the court; (vii) preliminarily and permanently enjoin Plaintiffs, their officers, agents, servants, employees,

attorneys, successors and any person who acts in concert or participation with Plaintiffs from using the '783, '499, '520, '667, '401, '948, '740, and '060 patents to block, hamper, hinder or obstruct FDA approval of the products described in ANDA No. 208269; and (viii) award to Alvogen such further relief as the Court may deem necessary, just and proper.

6. Amendment Of Pleadings

The Parties propose a November 3, 2016 deadline for the amendment of pleadings.

7. Joinder Of Parties

The Parties propose a November 3, 2016 deadline for joinder of parties.

8. Discovery

The Parties have not yet taken discovery in this action. Subject to the Court's approval, the Parties propose that fact and expert discovery shall be conducted according to the schedule set forth in Exhibit A.

a. Plaintiffs' Position

Preparation of Plaintiffs' case will require extensive discovery and analysis of technical documents and physical materials that Plaintiffs will seek from Defendant. Plaintiffs bear the burden of proving infringement by the Alvogen Generic Product, formulations that have not previously existed and are not publicly available. Plaintiffs also intend to seek other discovery typical in ANDA patent infringement actions, which may include discovery involving third parties that participated in the production of the accused generic products or their ingredients.

To satisfy their burden of proof, Plaintiffs (i) will require access to technical documentation in the possession of Alvogen, its affiliates, and any relevant third parties, including, at a minimum, ANDA No. 208269, any associated correspondence with the FDA, and

any Drug Master Files relied on in connection with that ANDA; and (ii) may require access to physical samples relating to the Alvogen Generic Product. These physical samples may be necessary for scientific testing to determine whether the Alvogen Generic Product, as made, imported, offered for sale or sold by Alvogen, or as used by patients, caregivers, or other end users, will infringe the patents-in-suit.

b. Defendant's Position

Preparation of the Defendant's case will require fact and expert discovery on all issues raised by the Complaint, Answer and Counterclaims. Alvogen bears the burden of proving that the patents-in-suit are invalid.

Alvogen will require discovery related to the following: (i) Plaintiffs' research and development of its hydrocodone bitartrate products, including but not limited to Hysingla[®]; (ii) research and development of all related Orange Book patents; (iii) prosecution of all related Orange Book patents and any non-U.S. counterpart applications; (iv) research and development regarding the filing of NDA No. 206627, as well as all IND applications relating to hydrocodone bitartrate; (v) Plaintiffs' communications with FDA regarding NDA No. 206627 and any supplements or amendments thereto, as well as all IND applications preceding the NDA; (vi) Plaintiffs' allegations of infringement of the patents-in-suit; (vii) Plaintiffs' allegations of the validity of the patents-in-suit; (viii) licensing of the patents-in-suit; (ix) prior art to the patents-in-suit; (x) Plaintiffs' knowledge of invalidity of the patents-in-suit; (xi) any secondary considerations that Plaintiffs' intend to rely on to rebut obviousness; and (xii) additional discovery as may be required and/or identified during discovery.

c. Discovery Limitations/ESI

The Parties agree to limit the number of interrogatories and the number and duration of depositions in accordance with the Federal Rules of Civil Procedure. The Parties also agree that, where possible, depositions of non-Parties will be held at offices near the witnesses or at a location mutually agreeable to the Parties and that depositions of Party witnesses will be held at the offices of their counsel or at a location mutually agreeable to the Parties.

The Parties further agree that no document created after the filing of this lawsuit or the related cases, or specifically developed in preparation for this lawsuit or the related cases, must be listed on a privilege log.

The Parties agree that copies of patent file wrappers downloaded from the United States Patent and Trademark Office (the “PTO”) website can be used in lieu of, and will be treated as having the same evidentiary value as, certified file wrappers obtained from the PTO.

The Parties will work together in good faith and anticipate reaching agreements regarding the scope of electronic discovery in the interest of minimizing the burden and expense on all Parties. In addition to any agreements reached by the Parties, including those set forth herein, the “Default Standard for Discovery, Including Discovery of Electronically Stored Information (“ESI”),” will apply.

9. Estimated Trial Length

Plaintiffs estimate that trial will take approximately twelve (12) six-hour days of trial. Defendant estimates that trial will take approximately nine (9) six-hour days of trial.

10. Jury Trial

At this time, Plaintiffs are not aware of any Seventh Amendment right to a jury trial, but reserve the right to request one should the situation arise.

11. Settlement

To date, there have not been settlement discussions between Plaintiffs and Defendant. The Parties will keep the Court apprised of any developments or progress made with respect to settlement.

12. Other Matters

There currently are three pending cases before the Court involving Abbreviated New Drug Applications seeking approval to market a generic version of Plaintiffs' Hysingla[®]. This case, C.A. No. 15-687 (GMS), as well as C.A. No. 15-784 (GMS), involve the same Parties and ANDA (the "Alvogen Cases"). A similar case, also involving an ANDA seeking approval to market a generic version of Plaintiffs' Hysingla[®], is pending against Actavis Laboratories FL, Inc. ("Actavis") and the same patents-in-suit, C.A. No. 15-686 (GMS).

Additionally, both Alvogen and Actavis recently provided Plaintiffs with a new ANDA patent Paragraph IV certification pursuant to the Hatch Waxman Act concerning patents recently listed in the Orange Book, and Plaintiffs are currently considering whether to bring an additional suit against Alvogen and/or Actavis. If Plaintiffs do not commence new suits against Alvogen related to any new ANDA patent Paragraph IV certification made pursuant to the Hatch Waxman Act, Alvogen may seek declaratory judgment of non-infringement and/or invalidity, pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, the Patent Laws of the United States, 35 U.S.C. §1, et. Seq., 35 U.S.C. § 271(e)(5), and 21 U.S.C. § 355(j).

The Parties propose consolidating the three pending cases and considering further case consolidation if and when additional lawsuits are filed concerning the two pending ANDAs.

The Parties propose that a protective order is necessary due to the existence and likely exchange of confidential information in this action. The Parties propose to present a

stipulated protective order to the Court for its consideration no later than fifteen (15) days after the Rule 16 Conference.

The Parties propose that any documents due under the case schedule must be served no later than 6:00 pm Eastern Time on the dates upon which they are due in accordance with Delaware local rules.

13. Confirmation Of Conference

Counsel for the Parties met and conferred by telephone on September 30, 2015 and October 13, 2015, with respect to each of the matters addressed above.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP PROCTOR HEYMAN ENERIO LLP

/s/ Rodger D. Smith II

Jack B. Blumenfeld (#1014)
Rodger D. Smith II (#3778)
1201 N. Market Street
P.O. Box 1374
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
rsmith@mnat.com

*Counsel for Plaintiffs and Counterclaim
Defendants
Purdue Pharma L.P.,
Purdue Pharmaceuticals L.P.,
The P.F. Laboratories, Inc., and
Grünenthal GmbH*

OF COUNSEL:

Jeffrey I. D. Lewis
Justin M. Ross
Naz E. Wehrli
Andrea McChristian
FRIED, FRANK, HARRIS, SHRIVER
& JACOBSON LLP
One New York Plaza
New York, NY 10004-1980
(212) 859-8000

/s/ Dominick T. Gattuso

Dominick T. Gattuso (#3630)
300 Delaware Ave., Suite 200
Wilmington, DE 19801
(302) 472-7300
dgattuso@proctorheyman.com

*Counsel for Defendant and Counterclaim
Plaintiff
Alvogen Pine Brook, Inc.*

OF COUNSEL:

Matthew J. Becker
Jeremy C. Lowe
Stacie L. Ropka
AXINN, VELTROP & HARKRIDER LLP
90 State House Square
Hartford, CT 06103
(860) 275-8100

*Counsel for Defendant and Counterclaim
Plaintiff
Alvogen Pine Brook, Inc.*

*Counsel for Plaintiffs and Counterclaim
Defendants
Purdue Pharma L.P.,
Purdue Pharmaceuticals L.P., and
The P.F. Laboratories, Inc.*

Basil J. Lewris
Jennifer H. Roscetti
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4150
Counsel for Plaintiff Grünenthal GmbH

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